

REMARKS

The present response canceled claims 15, 16, and 20 without prejudice or disclaimer as to the subject matter recited therein. In addition, claims 29-31 have been added and the specification has been amended to correct a typographical error. Claims 17-19, 21, 22, and 29-31 remain pending in the captioned case. Further examination and reconsideration of the presently claimed application are respectfully requested.

Objection to the Specification

An objection was lodged against the specification for an informality. In response thereto, claim 15 has been canceled in favor of new claim 29. Independent claim 29 does not contain the objectionable subject matter. Accordingly, Applicants respectfully request removal of this objection.

Section 102/103 Rejections

Claims 15, 16, and 20 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,988,350 to Herzberg (hereinafter “Herzberg”). In addition, claims 15, 16, and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,409,489 to Sioufi (hereinafter “Sioufi”). Applicants note that claims 15, 16, and 20 have been canceled rendering rejection thereto moot. However, Applicants present the following arguments pertaining to the patentability of new independent claim 29 over the cited references. Support for added claim 29 is set forth in the present specification, for example, page 3, lines 24-26 (stabilizing a fracture of an upper arm head or proximal upper arm), page 13, lines 1-3; page 17, line 25 - page 18, line 7 (one-piece plate), page 12, lines 10-12; Fig. 1 (bone screws on both the head-end portion and the shaft-end portion) page 6, line 5 (receiving members allowing passage and tightening of cerclage wires or sutures), page 4, lines 2-5; page 5, lines 7-8; page 12, lines 24-30; Fig. 1A (receiving members being disposed on the head-end portion surface which is opposite and substantially parallel to the bone-facing surface and faces away from the bone), page 10, lines 25-30; page 16, line 16 (thickness of the plate).

The standard for “anticipation” is one of fairly strict identity. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art of reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP 2131. Furthermore, anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, as arranged in the claim. *W.L. Gore & Assocs. V. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). Moreover, to establish a case of *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (C.C.P.A 1974), MPEP 2143.03. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed.Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), MPEP 2143.01. Using these standards, Applicants contend that the cited art fails to teach or suggest all features of the currently pending claims, some distinctive features of which are set forth in more detail below.

The cited art does not teach or suggest a one-piece plate member having a head-end portion and a shaft-end portion. Present independent claim 29 describes a one-piece plate member formed of unibody construction. For example, the plate member is formed from a sheet of rigid material, such as sheet metal (Specification -- pg. 13, line 1 - pg. 18, line 20; Figs. 13-16). As shown in more detail in present Fig. 16, a sheet of steel, titanium, or titanium alloy is rolled then cut or punched to form a one-piece plate made up of a head-end portion and a shaft-end portion (Specification -- pg. 16, line 7 - pg. 19, line 31).

Contrary to claim 29, Sioufi describes a compression plate 73 made up of separate cutting blades 77 affixed to a proximal end 82 (Sioufi -- col. 5, lines 19-25; Fig. 8A). The blades 77 are not formed as a single unibody structure along with proximal end 82 or the compression plate 73 in general (Sioufi -- Figs. 8A-8B). Likewise, legs 22 and 23 of Herzberg are not formed as a single extruded sheet material along with the plate-shaped section 25 (Herzberg -- col. 6, lines 29-52; Figs. 17-18).

The cited art does not teach or suggest a plate member having a substantially uniform thickness of 0.5 to 6.5 mm. Present independent claim 29 describes a specific thickness of the strip material which forms the plate member. The thickness can vary, but is preferably between 0.5 to 6.5 mm as set forth in the present specification (Specification -- page 16, lines 15-16; page 12, lines 4-5).

Contrary to the presently claimed thickness, nowhere is there any mention in Herzberg of the desired thickness of the plate-shaped section 25 or any other section. Moreover, nowhere is there any mention in Sioufi of the thickness for compression plate 73 or any of the other various items needed for the mounting kit, for securing plate 73 to a patient's femur M. Absent any suggestion of a desired thickness, a skilled artisan would derive that the desired thickness must be much greater than that which is claimed. As stated throughout the cited references, the apparatus, kit, compression plate, or any other apparatus being used is specifically targeted for a femur, femoral head, or human hip. The weight bearing forces on the femoral head, neck, or hip area are substantially greater than the claimed upper arm head and upper arm bone. Thus, a skilled artisan would know to substantially increase the thickness in the leg and hip region of a securing plate member in Herzberg and Sioufi, above and beyond that which is presently claimed. As will be described in more detail below, the application of the securing device in Herzberg and Sioufi, and the reason for that securement, is distinctly different from and bears different demands and structural support requirements than the presently claimed apparatus.

The cited art does not teach or suggest a bone-facing surface of the head-end portion and a bone-facing surface of the shaft-end portion bearing against outer surfaces of the upper arm head bone and the proximal upper arm bone. Present claim 29 makes clear that the head-end portion and the shaft-end portion each have surfaces. The bone-facing surface of the head-end portion bears against the upper arm head bone, while the bone-facing surface of the shaft-end portion bears against the proximal upper arm bone. This arrangement is more clearly illustrated in present Figs. 1B, 3A, and 3B as well as the corresponding text of the specification. For example, the head-end portion 2 of implant plate 1 is secured to the upper arm head bone, while the shaft-end portion is secured to the upper arm bone just beneath the upper arm head, as shown in Figs. 1B and 3B. Thus, claim 29 makes clear that various portions of the

implant plate bear against separate and distinct portions of an arm bone -- specifically, the upper arm head bone and proximal upper arm bone.

Contrary to claim 29, the cited art makes no reference to or distinguishes between portions of a plate, shaft, stabilization unit, or any other stabilization compression mechanism that bears two separate portions, each of which is applied against separate and distinct regions of a bone, much less an upper arm bone. When reading the cited art, a skilled artisan would clearly note that no distinction is made between portions of an affixing apparatus placed against distinguishable portions of a bone. Moreover, a skilled artisan would be taught that the only bone to which Herzberg and Sioufi are dimensioned to apply is the femur or hip bone. The problems of securing a femur or hip bone are altogether different from the present securing of an arm. Thus, the structure and overall configuration as claimed necessitates patentable distinctions from the femur/hip securing device of Herzberg and Sioufi.

The cited art does not teach or suggest a receiving member comprising a tube, an eyelet, a round hook, or a hole, each defining a substantially circular and circumferentially enclosed aperture through which wire cerclage or suture material may be inserted, threaded, or passed. As described in present claim 29, the receiving member has a particular configuration. The configuration is supported by that shown in the present specification, for example, present Fig. 4B illustrates a tubular-shaped receiving member 16, Fig. 6B illustrates an eyelet-shaped aperture 7, Fig. 9B illustrates a round-hook shaped receiving member 25, or Fig. 11B illustrates a drill hole 23. Specifically, the receiving member as claimed is not only circumferentially enclosed, but also is dimensioned to receive a wire cerclage or suture material.

Contrary to claim 29, there are no receiving members in Sioufi that receive a wire cerclage or suture material. Instead, holes 85 receive screws and eyelets 88 receive the rigid end of two threaded screws 99 (Sioufi -- col. 8, lines 55-60; col. 9, lines 21-26). Nowhere in Sioufi is there any mention that a receiving member can receive a wire or suture, or that the receiving member is dimensioned to receive such wire or suture. The shortcomings of Sioufi are compounded in Herzberg. While perforations 30 serve to accommodate "fastening nails or screws," it is the slot-shaped cutouts 129 (which are not the claimed tube, eyelet, round hook, or

hole) that receive cerclage wires (Herzberg -- col. 6, lines 50-54; col. 9, lines 36-60; Figs. 17-18). A skilled artisan would certainly appreciate the difference between a slot-shaped cutout 129 of Herzberg and a circular and circumferentially enclosed aperture as presently claimed. Moreover, a skilled artisan would also appreciate that wires or sutures can slip out of or become dislodged from a cutout, whereas the wires or sutures cannot be dislodged from the presently claimed circumferentially enclosed aperture or hole. Furthermore, the wires or sutures cannot be drawn at various angles across the slot; thus, the application of Herzberg is significantly limited compared to that of the present claims. Certainly, dislodgment would be a significant risk associated with Herzberg, but not be a risk for the improved device and structure presently claimed. The significance of long-term reliability and securement in the readily movable region of the upper arm is of paramount importance, and the prior art teachings of Herzberg would prove unsatisfactory to those skilled in the art.

The cited art does not teach or suggest a receiving member disposed on a head-end portion opposite the bone-facing surface. Claim 29 describes that the raised receiving member extends perpendicularly outward from the head-end portion (Specification -- Fig. 1B). The receiving member 6 is shown having an aperture 7 extending from the surface of the head-end portion opposite the surface on which the head-end portion bears against bone 4.

Applicants respectfully disagree with the statements made on page 6 of the Office Action. Specifically, Applicants disagree that it would be obvious to one having ordinary skill in the art to modify Sioufi so that eyelets 88 extend perpendicularly outward from the head-end portion opposite the surface at which the head-end portion bears against bone. Sioufi clearly shows eyelets 88 not extending from the head portion nor from the surface of the head portion opposite that which bears against bone. Instead, eyelets 88 in Sioufi extend from the lateral surface of the shaft region of compression plate 73 -- for good reason. Eyelets 88 must extend from the lateral extents or side surfaces of the shaft region because they are dimensioned to receive the threaded screws 99 of hook member 93 (Sioufi -- Fig. 9). Hook member 93 extends around the femoral bone and, more specifically, the proximal femur D (Sioufi -- Fig. 1). When placed, plate 101 bears against the surface of the femur and on the opposite surface of the femur is plate 73. In particular, eyelets 88 receive threads 99 so that the bone is secured between coupling plate 101 and compression plate 73.

In order to effectuate the coupling of hook member 93, it is required that eyelets 88 extend from the lateral surfaces of the shaft portion of compression plate 73 – not the claimed head portion or head portion surface opposite the head portion surface that abuts against bone. If Sioufi were modified so that eyelets 88 extend from the head portion, then it would be impossible for hook 93 and rigid threads 99 to have access to eyelets 88 since access is mandated from the opposite side of the femoral bone. Therefore, the proper test in determining obviousness of the teachings of Sioufi is to examine Sioufi through those skilled in the art to determine if Sioufi can be modified. If, however, the proposed modification would change the principle of operation of Sioufi or render its use unsatisfactory for its intended purpose, then the Examiner is instructed to disregard Sioufi as a reference that would render the claims unpatentable. *See, In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984); *In re Ratti*, 270 F.2d 910 (CCPA 1959); MPEP 2143.01.

The cited art does not teach or suggest a receiving member being an aperture having a central axis disposed to extend substantially parallel to the head-end portion and facing away from the bone, and also parallel to the edge of the head-end portion to which the receiving member is closest. Present claim 29 not only describes an aperture having a central axis that extends parallel to a surface of the head-end portion facing away from bone, but also describes the central axis being parallel to the edge of the head-end portion to which the receiving member is closest. For example, if one were to examine present Figs. 1A and 1B, apertures 7 of receiving member 6 include a central axis (shown by a shortened line through aperture 7). The shortened line of at least one aperture 7 of at least one receiving member 6 is shown to be parallel not only to the surface of the head member opposite that which bears against bone, but also parallel to the lateral extent of the head-end portion to which the receiving member 6 is closest. For example, the lateral extent closest to receiving member 6 is that extent or edge to which the axis is parallel (Specification -- Fig. 1A).

Contrary to present claim 29, instead of the aperture of eyelets 88 in Sioufi forming a central axis parallel to an edge of the head-end portion, the central axis of eyelets 88 extends perpendicular to the lateral extents and, more specifically, a line which forms the lateral extents of the first and second head sides (Sioufi -- Fig. 8A). Although the Examiner has carefully drawn a configuration on page 6 of the Office Action, Applicants wish to note that the central axis of the receiving

member/eyelet 88 (as drawn) is not parallel to the edge of the head-end portion to which the receiving member is closest, nor is the central axis parallel to the surface of the head-end portion facing away from the bone.

For at least the foregoing reasons, Applicants assert that claim 29 and claims dependent therefrom are patentably distinct over the cited art. Accordingly, Applicants respectfully request removal of this rejection and approval of new claims 29-31.

Request for Consideration of Withdrawn Claims 17-19, 21, and 22

Pursuant to the provisional election of the Species I directed to the embodiments of the implant plate (i.e., the species described in Figs. 1A, 3A, 5, 13, 14, and 15) noted in a previous response to an Office Action Mailed November 10, 2005, Applicant respectfully requests that upon allowance of a generic claim (i.e., new claim 29), that the species set forth in claims 17-19, 21, and 22 be allowed under 37 C.F.R. § 1.141(a).

CONCLUSION

The present amendment and response is believed to be a complete response to the issues raised in the Office Action mailed January 17, 2007. In view of the remarks herein, Applicants believe pending claims 17-19, 21, 22, and 29-31 are in condition for allowance. If the Examiner has any questions, comments or suggestions, the undersigned attorney earnestly requests a telephone conference.

No fees are required for filing this amendment; however, the Commissioner is authorized to charge any additional fees which may be required, or credit any overpayment, to Daffer McDaniel, LLP Deposit Account No. 50-3268.

Respectfully submitted,
/Kevin L. Daffer/
Kevin L. Daffer
Reg. No. 34,146
Attorney for Applicant(s)

Customer No. 35617
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